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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/314,206	05/19/1999	JOHN D. MENDLEIN	SONIC-007.00	4869

23483 7590 07/29/2004

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EXAMINER	
JAWORSKI, FRANCIS J	
ART UNIT	**PAPER NUMBER**
3737	28

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/314,206	Applicant(s) MENDLEIN ET AL	
	Examiner Jaworski Francis J.	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,30-35,60-62,70 and 82-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,30-35,60-62,70 and 82-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 20-29, 36 – 59, 63 – 69 and 71 – 81 have been cancelled. Claims 1-19, 30-35, 60 – 62, 70 and 82 –87 are present for examination in this case.

[Parenthesized numerals pertain to the specific claim or claims being rejected.]

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3,5, 9, 12-17, 19, 30 –35, 60-62, 70, 82-87 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Kami et al (US5176140) in view of Boyd et al (US4796632, of record) or Curtis et al (US4815470). The former teaches in its prior art Fig. 1 that a generic ultrasound probe in one adaptation would include a shaped holder 103 which in turn necessarily contains a closed-bottom acoustically transmissive interrogation window (so the ultrasound can exit) and an attachment portion in association with walls 103 (so the cap doesn't fall off). Such a protective cap assembly is adapted to minimize the distance between the transducer 105 and the probe interrogation surface to less than 1cm by direct apposition therebetween as well as prevent direct contact between the probe and the skin. Kami does not specifically identify a securing portion or a sonolucent film in association with these components. It would have been obvious however in view of Boyd et al elements 18, 20, 22 to attach

the Kami et al endcap with a securing means so that it does not fall off, and to make an acoustic window thin so that it is transparent to reflection artifact. The fact that Boyd et al include an intervening standoff delay does not negative the generic applicability of cap securement and sonolucency. Alternatively, it would have been obvious in view of Curtis et al elements 76, 208, 210, 212 to provide a latex hygienic film on a transducer cap so that at least some couplant can be added to provide shape conformance while maintaining a bacterial barrier, the amount of film standoff distance being a continuum including less than one cm dependent upon the anatomic size of the body passage, and to further provide detents for securing the sheath to the probe. The fact that Curtis et al is adapted for body cavity use does not negative use on epithelial or skin regions of body orifices. (Claim 1).

Kami et al advocate endcap components made of molded polymer resins, see Col. 5 lines 53-58; Boyd et al advocate silicone rubber/elastomer/plastic molded (polymer) components; Curtis et al use shaped or molded latex polymer as convenient low-cost covering components such as . (Claims 2, 9, 12).

Since in the case of each reference regions of the sidewall or endcap portions are thicker than the window portion then the window portion is necessarily more flexible. In Boyd this creates shape conformance; in Curtis et al this permits selective inflation of the window region by fluid to complete coupling. Otherwise the use of molding/injection molding insofar as the process might impart structure specificity is discussed above, and gel use in the device interior is taught by Boyd et al and would have been an

inherently obvious latex filler in Curtis et al, the terms 'machine applied' being structurally non-limiting in claim 61.. (Claims 3, 5, 60-62).

In all instances the interrogation window is sized to the ultrasound probe transducer forward face which is its interrogation surface, since there would be a maneuverability detriment or encumbrance to have an oversized cap window and an imaging detriment to have an undersized one. (Claims 13, 16).

The securing portions in the secondary references are characterizable as 'securing members' since each in turn has plural discrete parts or contact surfaces. (Claim 14).

In all references the holder has regions of greater cross-sectional thickness than the window as noted above – for example in Kami et al the sidewalls; likewise in Boyd et al; and the end-cap in Curtis et al. (Claim 15).

A skin application probe such as the case with any of the base references would reasonably be 3cm x 3cm since it must be applicable between the ribs or on a keck artery or within the confines of body orifices. (Claim 17).

Judicial notice is taken of the fact that components which must serve as sterility or hygienic barriers during clinical procedures are often stored in hygienic packages prior to use because of the infection risks. (Claim 18).

Since in Kami et al the end-cap is funnel-shaped it's contours are adapted for telescoping into another such cap, the arguments regarding holder structure otherwise being as above. (Claim 19).

Kami et al may be regarded as an acoustically transparent probe end-cap which is adapted to not have a significant standoff distance between transducer and

interrogation window. The secondary teachings of Boyd et al or Curtis et al then supplant the Kami et al teaching where it is silent as to removability via sliding fit since they are hygienically insertable over and removable from the ultrasound probe. (Claim 30).

Otherwise the arguments regarding molding and sonolucency set forth above apply. (Claim s 31 – 32, 35).

Since both the silicone rubber used in Boyd et al and the latex polymer in Curtis et al were known to be substantially fully sonolucent the rigidity of the selected film would be a function of selected film thickness to inhibit tearing based upon application and critically to the routineer. (Claim 33).

In both Kami et al and Boyd et al the end-cap would remain substantially planar at least if placed upon a planar surface in the shape-conforming case of the latter. (Claim 34).

Since while Kami et al does not afddress manner of over-fit and securement, both Boyd et al and Curtis et al teach in effect stretchable overfit of a collar-like portion of the probe holder, and this necessarily means that the holder is capable of use with a probe lot of at least some dimensional variation. (Claims 70, 82-83).

In Kami et al the interior and exterior surfaces are parallel and are both planar in the Fig. 1 profile view. (Claim 84).

During stretching associated with the aforementioned Boyd et al, Curtis et al overfits, at least some compression of secorement portions would occur hence these portions

would be fairly characterizable as'compressible members', the arguments against the parent claims being otherwise as above.. (Claims 85-87).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kami et al in view of Boyd et al or Curtis et al as applied to claim 3 above, and further in view of Lyon et al (US5897503, of record). Whereas the former are silent as to the manner of sealing the film or cap to the sidewalls, insofar as this process may be interpreted as imparting a novelty to the assembled structure beyond a process such as molding, it would have been obvious in view of Lyon et al to use heat adhesion to assemble components since selected materialw may be made to controllably shrink to desired sizes and fits in this manner. (Claim 4).

Claims 6-8, 10-11are rejected under 35 U.S.C. 103(a) as being unpatentable Kami et al in view of Boyd et al or Curtis et al as applied to claim1 above, and further in view of Larson et al (US6039694). The former are silent as to a construct in which the shaped holder is for example planar and open-bottom windowed and accepts the sonolucent film. It would however have been obvious in view of Larson et al, which antedates the PCTUS98/17242 8/1998 filing date believed to be the effective date for this hygienic film feature, to provide a hygienic film 4 in such fashion in order to obtain

high shape conformance and lubricity between the interfaces on both of its surfaces.(Claim 6).

The film as modified by Larson et al would be planar when applied to a foot-type probe such as Larson et al Fig. 3 or to the Kami et al type shown in Larson et al as Fig. 5 (Claims 7, 8).

Whereas the base references do not discuss exterior gel use, Larson et al evidences in extensive discussion that couplant gel on the (skin) interrogation side of a window surface was widely used in conventional ultrasound body surface scanning such that it would have been obvious to practice same with respect to Kami et al. (Claim 10).

Both Boyd et al and Larson et al (in its col. 1 discussion)also teach use of interior coupling gel in this regard. (Claim 11).

Response to Amendment Arguments

Amendatory language to the base claims has mooted the prior rejection arguments. Since probe end-cap arrangements were heretofore practiced without standoffs (Kami et al) or with offset only sufficient to contour-couple the window film to the apposed both surface (Curtis et al), applicants' newly introduced limitations do not serve to create patentable subject matter.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

Francis J. Jaworski
Primary Examiner

FJJ:fjj

07-24-2004